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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/918,568      | 08/01/2001  | Yoshinobu Okuno      | 2001_0977           | 4882             |

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EXAMINER

NAVARRO, ALBERT MARK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1645

DATE MAILED: 06/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/918,568

Applicant(s)

Okuno et al

Examiner

Mark Navarro

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1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-30 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 20-30 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 20-23, drawn to DNA, classified in class 536, subclass 23.1.
  - II. Claims 24-28, drawn to polypeptides, classified in class 530, subclass 350.
  - III. Claim 29, drawn to a method of immunization, classified in class 424, subclass 184.1.
  - IV. Claim 30, drawn to methods of producing a monoclonal antibody, classified in class 435, subclass 2.

Additionally, groups I-IV are further restricted according to MPEP 803.04 which sets forth that biological molecules with different sequences are distinct inventions. Consequently, Applicant is restricted to a single protein sequence, if electing protein claims, or a single nucleic acid sequence, if electing DNA claims. The generic claims will be examined in their entirety, however, only claims which read upon the elected sequence will be examined.

The inventions are distinct, each from the other because of the following reasons:

Invention I drawn to a DNA molecule, and Invention II drawn to a polypeptide molecule are distinct since they are products with different structure and biological properties. The protein is made of amino acids whereas the nucleic acid molecule consists of nucleotides. Further

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methods known in the art used to make the polypeptide require different reagents and parameters from the methods of making nucleic acid encoding the protein and the method of making the polypeptide does not require the nucleic acid. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography.

Invention II, drawn to a polypeptide and Invention III, drawn to methods of immunization are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide may be administered in vivo as claimed to elicit an immune response, or alternatively may be incorporated into an in vitro assay to screen for the presence of antisera.

Invention IV, drawn to methods of producing a monoclonal antibody is distinct from Inventions I-III, since it requires additional biological reagents and parameters for isolating the correct B lymphocyte and fusing it to a myeloma cell line.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225.



Mark Navarro

Primary Examiner

June 19, 2003